

U.S. Department of Health and Human Services  
**Office of Inspector General**



# FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing

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September 2022, OEI-01-20-00380





### Why OIG Did This Review

At the start of the COVID-19 pandemic, no test existed to identify this novel virus. Testing is vital to diagnose infected individuals and understand spread during infectious disease emergencies. The Food and Drug Administration (FDA) used its Emergency Use Authorization (EUA) authority to facilitate the development and availability of COVID-19 tests. Members of Congress have expressed strong interest in the availability and effectiveness of both diagnostic and serology tests. This review assesses how FDA used its EUA authority to authorize COVID-19 tests during the crucial first months of the pandemic.

### How OIG Did This Review

We focused our review on the early months of the pandemic: January 1 through May 31, 2020. We relied on FDA documents, data, and interviews to determine how FDA conducted EUA activities and decision-making. We surveyed and received responses from 237 test developers that engaged with FDA about their COVID-19 tests and analyzed survey responses to assess experiences working with FDA. We also interviewed test developers and representatives from a professional laboratory association for context about developer experiences.

## FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing

### Key Takeaway

From January through May 2020, FDA repeatedly adapted its approach to how it used Emergency Use Authorizations to address COVID-19 testing challenges and to expedite access to tests. However, these efforts to increase test availability sometimes came at a cost to test quality.

of quality.

When COVID-19 emerged, ensuring that tests were available to diagnose and track it became a vital public health goal. FDA used its EUA authority to authorize tests and to help ensure that the nation's testing needs were met. The EUA authority allows for a lower level of evidence for emergency medical products compared to during nonemergency situations. EUAs generally entail a shorter review period while maintaining an appropriate assurance

Over the first 5 months of the pandemic, FDA issued over 100 EUAs for COVID-19 diagnostic tests, which identify an active infection, and serology tests, which identify prior infection. Because of the different purposes of these types of tests, FDA used different approaches to ensure that tests got to the market quickly and performed well.

### What OIG Found

The failure of the Centers for Disease Control and Prevention (CDC)'s first test rollout revealed vulnerabilities in the Federal approach to testing early in the COVID-19 pandemic. It is typical for CDC to be the first to receive an EUA, and FDA expected that CDC's test would meet the early testing needs of the nation. However, CDC's first test was unusable for many for weeks while no other test was authorized. Furthermore, due in part to its limited engagement with the public health labs that were using CDC's test, FDA was slow to realize that testing by public health labs was far more limited than it initially expected. To address problems with the first authorized COVID-19 test, FDA worked with CDC, including allowing CDC to modify the terms of its original EUA. However, preventing a similar problem from occurring in future emergencies would require actions outside of FDA's authority alone.

In using its EUA authority, FDA also made calculated decisions to increase availability of COVID-19 testing, but these decisions often came at a potential cost to test quality. FDA authorized tests using lower levels of evidence to support developers struggling to access clinical samples.

FDA's policies allowed diagnostic and serology tests to get on the market quickly; however, that resulted in some problematic tests on the market, requiring further action by FDA.

FDA's decision to accept all EUA requests resulted in a record number of submissions—often low-quality and from developers lacking experience with FDA's processes. In response, FDA took steps to support developers and ease its workload, which included issuing EUA guidance, updating templates (submission guides for developers requesting EUA), and adjusting its EUA review process, among others. Some developers still reported being frustrated and confused.

FDA's experience using EUA for COVID-19 tests during the first few months of the COVID-19 pandemic provided actionable insights about the EUA process as well as a national testing strategy.

#### ***Summary of Actionable Insights***

- FDA addressed early testing challenges using EUA flexibilities, but this experience underscores the need for a national testing strategy.
- FDA needs clear, direct communication with the lab community during an emergency.
- Developers require further FDA guidance on how to validate tests during shortages of clinical samples.
- Although policies that delay or forgo FDA review allow for faster testing, without FDA review problematic tests reach the market.
- FDA needs contingency plans for resources to handle the workload that the next emergency response may require.
- Templates are useful tools for FDA to communicate expectations for test development, validation, and authorization.
- Inexperienced test developers require more support from FDA during the EUA process.

#### **What OIG Recommends and How the Agency Responded**

Our findings underscore the need to apply actionable insights from FDA's early experiences with the COVID-19 pandemic toward current and future infectious disease emergencies to better balance test availability and quality. We recommend that FDA:

- Assess and, as appropriate, revise guidance for test EUA submissions

- Develop a suite of EUA templates for future emergencies involving novel pathogens
- Expand the FDA Center for Devices and Radiological Health's existing device-tracking platform to facilitate EUA submission and monitoring
- Expand and improve resources for test developers on the EUA process
- Establish formal communication channels between FDA and the lab community, to be used in emergencies that require testing
- Work with Federal partners to implement lessons learned about a national testing strategy that go beyond the EUA process

FDA concurred with all of our recommendations.

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# BACKGROUND

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## OBJECTIVE

To assess the effectiveness of FDA's use of emergency use authorization (EUA) to authorize tests for COVID-19.

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In December 2019, a novel coronavirus caused unusual cases of pneumonia-like illness in China. The illness soon came to be known as coronavirus disease 2019 (COVID-19).<sup>1,2</sup> The Centers for Disease Control and Prevention (CDC) confirmed the first domestic case of COVID-19 in a patient in Washington State on January 20, 2020, as the virus spread rapidly throughout the world. In response, the Secretary of Health and Human Services declared a public health emergency on January 31. The World Health Organization declared COVID-19 a pandemic on March 11, 2020, indicating that COVID-19 had spread to countries across several continents, potentially affecting a large number of people.<sup>3,4,5</sup> As of May 25, 2022, CDC had reported over 83 million cases in the U.S., and over one million deaths.<sup>6</sup>

Understanding how infectious diseases spread and whom they infect is paramount to containing transmission.<sup>7</sup> Testing is one of the most useful tools for disease surveillance and for researchers to gain knowledge of the disease such as how it is transmitted between individuals. Testing also allows diagnosed individuals to take preventive measures to limit transmission to others. Without sufficient testing, efforts to control a virus are significantly limited.

A diagnostic test for COVID-19 did not exist when the disease first began to spread; such is the nature of a novel pathogen. Therefore, the first step for governments and scientists around the world was to develop a diagnostic test.<sup>8</sup> Indeed, early in the outbreak, FDA stated that it was "actively working to facilitate the development and availability of" tests to diagnose COVID-19, in part through its Emergency Use Authorization (EUA) authority.<sup>9</sup>

FDA's response to the COVID-19 pandemic is informed by its experiences responding to outbreaks of the H1N1, Zika, and Ebola viruses. COVID-19 has presented many new challenges to FDA, and with that, many actionable insights. This report aims to evaluate FDA's use of its EUA authority during the crucial first months of the pandemic and to determine opportunities for improvement so that we are better prepared for future emergencies.

## FDA Emergency Use Authorization Authority

In part, FDA may use its EUA authority during a public health emergency to allow entities to distribute and use unapproved medical products (or unapproved uses of approved medical products) for the diagnosis, treatment, or prevention of serious or life-threatening diseases.<sup>10, 11</sup> This EUA authority allows FDA to facilitate these medical products' availability to respond to an emergency. Entities that request EUA for their product may seek full approval for the product after authorization.<sup>12</sup> To initiate FDA's EUA authority during COVID-19, the Secretary of Health and Human Services determined that a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad exists and, on the basis of this determination, declared that circumstances exist to justify EUA for certain products.<sup>13, 14, 15</sup> The Secretary made this determination regarding COVID-19 and declaration regarding tests for COVID-19 on February 4, 2020.<sup>16</sup> EUA for a product expires at the end of the relevant EUA declaration, which may extend beyond the public health emergency declaration, or sooner if FDA revokes the authorization.<sup>17,18</sup>

### Exhibit 1. FDA must ensure that a product meets four statutory criteria for EUA.

1. Condition/disease must be serious or life-threatening and caused by the agent referred to in the Secretary's declaration;
2. It is reasonable to believe based on the available scientific evidence that the product may be effective to prevent, diagnose, or treat such serious or life-threatening diseases or conditions caused by the agent referred to in the Secretary's declaration;
3. It is reasonable to believe based on the available scientific evidence that the product's known and potential benefits outweigh the known and potential risks, taking into consideration the material threat posed by such disease or condition; and
4. There are no adequate, approved, and available alternatives.

Source: Section 564 of the FD&C Act.

FDA's EUA authority allows for a lower level of evidence compared to the statutory criteria for approval or clearance through a traditional marketing pathway (see Exhibit 1).<sup>19</sup> Emergency product developers must demonstrate that there is a "reasonable belief that the product may be effective," rather than that there is a "reasonable assurance of safety and effectiveness."<sup>20, 21, 22</sup> However, developers must demonstrate a reasonable belief that "the product's known and potential benefits outweigh the known and potential risks."<sup>23, 24, 25</sup> This lower level of evidence allowed during public health emergencies enables FDA to review and authorize these products

more quickly than products approved or cleared through traditional marketing pathways.<sup>26</sup>

FDA's EUA authority also allows for broad flexibility during an emergency in how FDA will balance the need to facilitate the quick availability of medical products with ensuring that these products meet quality standards. FDA may do this by engaging with stakeholders early in an emergency to encourage them to develop and seek EUA for medical products, establishing a required format for EUA submissions, and determining how FDA reviewers process EUA requests. FDA may also be flexible with the kinds of evidence standards that developers must meet to receive EUA.

The COVID-19 response is FDA's most widespread use of EUA authority in response to a single threat, though the authority has existed since 2004.<sup>27</sup> FDA has used its EUA authority in response to such threats as Avian Flu in 2013 and the Zika Virus in 2016.<sup>28</sup> In response to the COVID-19 pandemic, FDA issued EUAs for a variety of medical products—first for a diagnostic test, and then others to authorize the emergency use of N-95 masks, ventilators, and other devices; drug treatments such as remdesivir; and three vaccines that are each biologic products.

## COVID-19 Test Regulation Within FDA

Within FDA, the Center for Devices and Radiological Health (CDRH) regulates medical devices, which include products ranging from tongue depressors to pacemakers.<sup>29, 30, 31</sup> CDRH approves and clears medical devices before they are marketed. It also works with the Office of the Chief Scientist to authorize emergency use of medical devices through the EUA pathway.<sup>32</sup> Three independent teams within CDRH review COVID-19 tests: one each for molecular, antigen, and serology tests.<sup>33</sup> Other teams carry out pre-authorization reviews and post-authorization compliance monitoring and surveillance.

## Requesting and Issuing an EUA for an Emergency Test

Before requesting EUA, developers have the option to engage with FDA via a pre-EUA process to determine whether their product meets FDA's EUA evidence standards. Developers can include government entities (such as CDC), commercial labs, and hospital labs. Pre-EUA activities typically involve FDA reviewing data and documents and providing feedback to developers to help ensure that their potential EUA request is complete and ready for formal FDA review.<sup>34, 35</sup>

To formally request EUA, developers must submit required documents to FDA (together, these documents are referred to as an EUA submission or request).<sup>36</sup> To receive EUA for a test, developers must meet FDA's evidence standards to demonstrate that their tests perform as intended (i.e., with a "reasonable belief" that they are effective).<sup>37</sup> Meeting these standards requires developers to submit validation data to assess the potential for false test results, which can impact the care of an individual patient and have public health implications.<sup>38</sup> If a developer intends

to manufacture a test for distribution, it must also specify the name(s) of the manufacturer(s) in their EUA request, which may include contract manufacturers.

Upon issuing EUA, FDA establishes conditions of authorization to protect public health and safety.<sup>39</sup> Developers must adhere to these conditions to continue using their test. For example, to ensure that health care professionals understand how to use tests and interpret test results, FDA establishes conditions that require developers to provide “Fact Sheets” with this information. FDA places conditions that require developers to collect information on the performance of their test and report suspected false test results to FDA. FDA also establishes conditions requiring test users, such as labs, to use the test as specified in the FDA-approved test labeling. To modify their test or how their test may be used, developers must formally request authorization for these changes from FDA.

## EUA Post-Authorization Oversight and Enforcement

FDA reviews authorized products to ensure that they continue to meet the conditions of authorization, including that their known and potential benefits outweigh their known and potential risks, and that products do not jeopardize public health and safety.<sup>40</sup> For COVID-19 tests, FDA post-authorization oversight also involves ensuring that all tests on the market have EUA (or do not require EUA to be on the market). FDA oversees them by monitoring product performance, watching for signals about the products from other sources, and receiving information from stakeholders.

FDA gathers information on tests in three ways: receiving allegations of regulatory misconduct from stakeholders, direct reporting from developers, and conducting its own surveillance. Allegations come from health care providers, patients, and other stakeholders, and can include reports of false results or mislabeled products. Reporting requirements include data on adverse events and test performance (e.g., false positives and false negatives), which developers submit to FDA as data become available. Finally, CDRH reviewers conduct surveillance, such as monitoring websites and promotional materials, for tests that are illegally on the market.

Reviewers begin a compliance investigation if they find evidence or receive allegations that a COVID-19 test is being distributed or used in a manner inconsistent with the letter of authorization. FDA may revoke an EUA if the test no longer meets the conditions of authorization or presents public health or safety concerns.<sup>41, 42</sup>

## Diagnostic and Serology COVID-19 Tests

FDA has authorized two general types of tests to diagnose current infection with, and presence of antibodies for, COVID-19: diagnostic and serology.<sup>43</sup> Diagnostic tests identify active infection with COVID-19. Serology tests determine whether a patient had COVID-19 by detecting antibodies in the blood, but should not be used to diagnose active infection.<sup>44</sup> See Exhibit 2 for details. These COVID-19 tests are in vitro diagnostic tests. This means that they use patient samples, such as blood or saliva, to indicate whether a patient has COVID-19 or COVID-19 antibodies.

## Exhibit 2. Types of COVID-19 tests

Test	Type	Detects	Used to	Result times
<b>Diagnostic</b>	Molecular	COVID-19 genetic material	Diagnose active COVID-19	Less than 1 day to 1 week
	Antigen	COVID-19 proteins	Diagnose active COVID-19	1 hour or less (may be less reliable than molecular tests)
<b>Serology</b>	N/A	Antibodies in the blood due to COVID-19	Indicate prior COVID-19. Should not be used to diagnose active COVID-19.	Less than 1 day to 3 days

Source: FDA, *COVID-19 Test Basics*.

Accessed at <https://www.fda.gov/consumers/consumer-updates/covid-19-test-basics> on September 2, 2022.

# Methodology

## Scope

This report focuses on the EUA process during the first few months of the COVID-19 health emergency. It includes all COVID-19 tests that FDA reviewed for authorization from January 1 through May 31, 2020, and oversight FDA conducted on those tests through December 31, 2020. Although FDA does not know the exact number, it estimates that by late May 2020 it worked with more than 400 developers through the pre-EUA and EUA processes and issued 117 EUAs for tests.<sup>45</sup> FDA has continued to issue EUAs after the review period of this evaluation. As of May 3, 2022, FDA issued EUAs for over 400 tests, including 348 diagnostic and 85 serology tests.<sup>46</sup>

To conduct this study, we relied on multiple data sources: public and internal FDA documents; interviews with test developers, FDA staff, and other stakeholders; and a survey of test developers.

## FDA Documents

We received data from FDA on its EUA policies and procedures, such as its standard operating procedures for EUAs; all policies and procedures for requesting, reviewing, and prioritizing EUA submissions; criteria for review decisions; and documents related to oversight and enforcement, among other data. We also received a log of all test developers that engaged in EUA and pre-EUA activities with FDA between January 1 and May 31, 2020. In addition, we acquired publicly available data, such as guidance documents, lists of tests that received EUA, and information on tests that were subject to oversight enforcement actions.

## Interviews

We conducted interviews with four test developers and 11 FDA staff members, including reviewers and officials within CDRH. We also conducted interviews with other stakeholders, including a former FDA official and staff from a professional laboratory association. We use the data from the test developer interviews as examples and to provide context, but do not use them to generalize to all test developers that sought EUA for COVID-19 tests.

## Test Developer Survey

We sent a web-based survey to all test developers that contacted FDA about the EUA or pre-EUA process between January 1 and May 31, 2020. FDA provided us with a list of all EUA and pre-EUA submissions, including a contact email address for each submission.

We sent our survey to all 967 unique email addresses on the EUA/pre-EUA log provided by FDA. However, FDA informed us that the 967 email addresses may not represent 967 unique test developers. Rather, some developers used unique email

addresses for each EUA or pre-EUA request they submitted, and others requested EUA or pre-EUA for the same test multiple times using different names. FDA also informed us that the log contains some test resellers and distributors that submitted EUA requests for tests that FDA had already reviewed. Therefore, we do not know (nor does FDA) the true population of unique test developers that contacted FDA about COVID-19 tests.

Many of the contact emails on the list FDA provided were for contractors that test developers hired to act as intermediaries for working with FDA. Several contractors submitted multiple EUA applications for multiple test developers. Because we sought information about test developers' direct experiences with FDA and the EUA process, we did not collect responses from contractors. Instead, we requested contact information for the test developers with whom they worked, but only 22 out of over 100 contractors responded. We sent the web-based survey to all test developers identified by the 22 contractors.

In total, 237 test developers responded to the survey.<sup>47</sup> Therefore, data from the survey represent the views and experiences of the 237 test developers that responded to our survey rather than all test developers that contacted FDA about an EUA for their test.

In the survey, we asked questions about the developers' experiences working with FDA, including whether FDA's guidance, processes, and policies were helpful or challenging. We also included several open-ended response options for developers to provide more context about their experiences.

## Analysis

We analyzed data provided by FDA to assess how FDA implemented EUA policies and procedures and to construct a timeline of significant events related to EUAs for COVID-19 tests in the first five months of 2020.

We analyzed interview data with test developers to inform the questions we asked in our test developer survey. We also analyzed the interview data and the survey results to provide context about the developer side of the EUA process.

## Limitations

The results of our test developers survey are not projectable and only reflect the experiences of the 237 test developers that responded to the survey.

Furthermore, we did not independently verify data provided by FDA, nor information provided by FDA or test developers in interviews.

## Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

# Significant Events in Developing Tests for COVID-19: January Through May 2020

For reference throughout the report, below are some key events that took place during the scope of our study, followed by an overview of early problems with CDC’s test.

Diagnostic Timeline	Serology Timeline
<b>January 2020</b>	
<b>20</b> First case of COVID-19 confirmed in U.S.	
<b>31</b> HHS Secretary declares public health emergency	
<b>February 2020</b>	
<b>3</b> FDA receives CDC’s complete data package in support of its EUA request	
<b>4</b> HHS Secretary declares that circumstances exist justifying EUAs to detect and/or diagnose COVID-19	
<b>4</b> FDA issues first diagnostic test EUA to CDC	
<b>5</b> CDC begins shipping its tests	
<b>8</b> Public health labs (PHLs) begin to report problems with CDC tests	
<b>10</b> CDC notifies FDA that there is a problem with the CDC test	
<b>21</b> FDA learns that only 7 PHLs have successfully verified their CDC test	
<b>24</b> APHL writes letter asking FDA to allow PHLs to create their own tests	
<b>26</b> FDA announces that it will allow certain PHLs to modify and use the CDC test	
<b>29</b> FDA issues EUA to Wadsworth Center, New York State Department of Health	
<b>29</b> FDA issues policy allowing certain qualified labs to use their own validated tests before requesting EUA	
<b>March 2020</b>	
<b>12</b> FDA issues first commercial EUA to Roche Molecular Systems, Inc.	
<b>12</b> FDA issues policy allowing New York State Department of Health to authorize labs testing in New York	
<b>16</b> FDA issues policy allowing all States to authorize labs testing within their State	<b>16</b> FDA allows serology tests on market without EUA as long as they meet certain requirements
<b>16</b> FDA issues policy allowing commercial manufacturers to develop, use, and distribute validated tests prior to EUA	
<b>April 2020</b>	
	<b>1</b> FDA issues first serology test EUA to Cellex, Inc.
	<b>17</b> FDA issues letter to health care providers about appropriate use of serology tests
	<b>18</b> FDA announces collaboration with National Institutes of Health, CDC, and Biomedical Advanced Research Development Authority to assess test performance
<b>May 2020</b>	
	<b>4</b> FDA issues policy requiring commercial manufacturers to request EUA prior to marketing
	<b>21</b> FDA begins removing unauthorized serology tests from its online list of permitted serology tests on the market

**Specific dates are in bold.**

## CDC's COVID-19 Test: Highlights of Early Problems

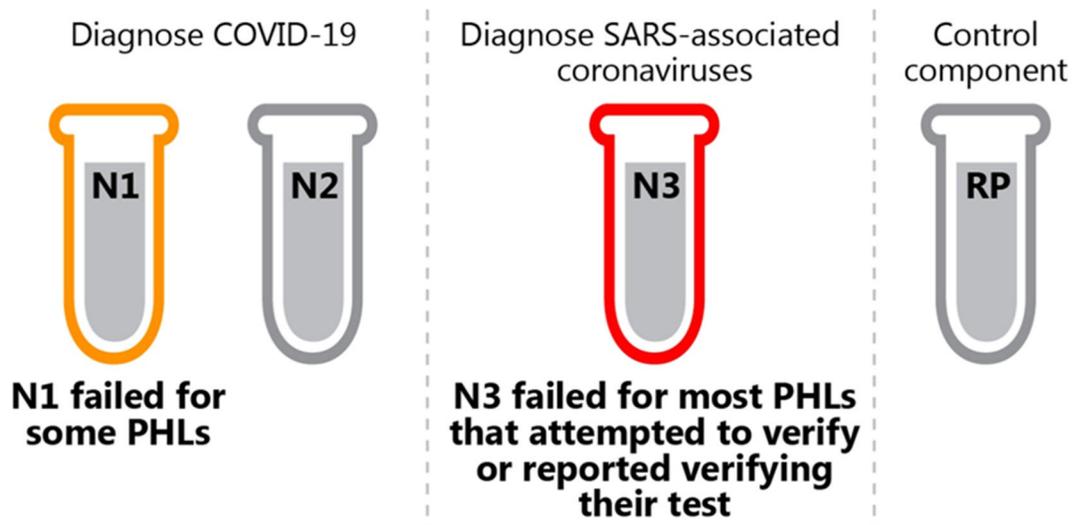
*CDC develops a test for COVID-19:* On January 9, 2020, FDA and CDC began discussing the COVID-19 pandemic, including CDC's progress toward developing a test.

*FDA authorizes CDC's test:* On February 4, FDA issued EUA for CDC's test, a day after receiving CDC's complete submission for authorization.

*PHLs report a problem with the test:* On February 10, days after CDC made its test available to 115 labs, including PHLs and Department of Defense (DoD) labs, CDC notified FDA that 10 PHLs were reporting problems with one of the four components of the test—the N3 component.<sup>48, 49</sup> Each component has its own function in the test. The N3 component was included to identify any virus in the coronavirus family that causes severe acute respiratory syndrome (SARS) in case COVID-19 mutates.

Two days later, CDC reported to FDA that 26 PHLs had problems with the N3 component. On February 15, CDC reported that additional PHLs had problems with the N1 component (on February 21, CDC clarified that six labs had issues with the N1 component). PHLs were unable to use tests that had problems; however, some labs, including CDC itself, were able to continue testing.

**Some PHLs reported problems with two components of CDC's test.**



# FINDINGS

## FDA used its emergency use authorization flexibilities to help resolve the failure of the CDC test rollout, but the engagement revealed vulnerabilities in the Federal approach to early emergency testing

As previously noted, FDA issued the first EUA for a COVID-19 diagnostic test to CDC on February 4, 2020. CDC was the first test developer to request and receive EUA, which is typical because CDC is often the first U.S. entity to obtain samples for novel pathogens. Obtaining these samples allows developers to validate their tests, a key element of an EUA request because it demonstrates that the test performs as intended.<sup>50</sup> Thus, CDC's early access to clinical samples gives it a considerable head start over commercial developers. Even so, CDC was not able to obtain a sample to validate its test until it identified a case in the U.S.

CDC's position as the only developer with an authorized COVID-19 test proved problematic when PHLs reported concerns with certain components of the test. Although FDA noted a robust pipeline of private developers interested in requesting EUA for COVID-19 tests in January and February 2020, CDC's was the only test in the nation with EUA until February 29. With no Federal plan to fill the gap in testing when the CDC test failed, FDA worked with CDC to solve the problems while continuing to engage with private developers.

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"We were working with CDC daily to explore various options to address the problems observed with their distributed test... We had reviewers on standby through the weekends, ready to review such requests." – FDA official

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FDA allowed modifications to CDC's existing EUA to address problems and increase testing. FDA and CDC agreed on a dual approach to resolving this issue; both approaches would require authorization from FDA. First, during a February 10 call, CDC told FDA that it suspected the problem occurred during the manufacturing process. To address this, FDA and CDC agreed that commercial vendors could manufacture CDC's test or problematic components of CDC's test. CDC initially used its own facilities to manufacture its COVID-19 test. FDA suggested that CDC request to include two contracted manufacturers in its EUA. Once FDA approved that, the contractors produced and distributed millions of CDC's tests within weeks. Second, on February 15, CDC began considering contingency plans that would require further modifications to its existing EUA so that PHLs could use the tests they had until the replacements arrived. On February 26, after receiving data from CDC confirming that dropping the N3 component would not adversely affect test results, FDA allowed

PHLs to drop the N3 component if they had problems with only this component of the test. FDA drafted proposed instructions for PHLs and, together with CDC, communicated that PHLs could proceed with testing in this way.<sup>51</sup>

FDA had to take additional steps to ensure that CDC's EUA modifications were appropriate. After learning on February 21 that CDC had not yet confirmed the cause of the problem, FDA immediately sent an official onsite to CDC laboratories to conduct FDA's own assessment. Identifying a manufacturing problem would allow FDA and CDC to continue with their approach to resolving this problem; identifying a design problem would require CDC to seek authorization for a new test. The FDA official ultimately concluded that CDC's test design was sound and the problem was caused by contamination during manufacturing.

Overall, to address the problems with the CDC test rollout, FDA used its EUA authority to an extent that it had not in previous emergency responses. Notably, FDA and CDC worked closely throughout February and March to pursue opportunities to expand access to testing under CDC's EUA. As one FDA official put it, "In all, there were several actions underway simultaneously, all of which were targeted to increasing testing capacity." See Exhibit 3 for other examples of how FDA engaged with CDC.

### **Exhibit 3. Examples of how FDA worked with CDC to increase the availability of diagnostic tests under CDC's EUA**

- Facilitated negotiations between CDC contract manufacturers to ensure that "research use only" tests could be offered for immediate clinical use under CDC's EUA.  
February 27: CDC's manufacturer began distributing hundreds of research use only tests.
- Proposed and encouraged CDC to allow other EUA developers to use CDC's test design and data to demonstrate that their test's performance is comparable to CDC's test.  
February 29: The New York State Department of Health received an EUA using this approach. This was expanded to all developers in March.
- Encouraged CDC to allow any lab to use kits manufactured under CDC's EUA.  
First week of March: Over 1 million tests released.  
Second week of March: Over 5 million tests released.  
Third week of March: Over 10 million tests released.

Source: Document submitted to the [Homeland Security & Governmental Affairs Committee](#) (2021).

Because FDA was only directly engaged with developers through its EUA process, FDA was slow to realize that testing within PHLs was far more limited than it had initially expected. Regarding authorized tests, FDA communicates directly with developers, not with the labs implementing them. For this reason, FDA was not initially engaged with PHLs. As a result, FDA was unaware that testing within PHLs was very limited and may not have provided sufficient testing. FDA assumed that dozens of PHLs, in addition to CDC, were using CDC's original test and could meet the testing needs of the nation until other test developers received authorization for their own tests.

However, FDA learned from media sources that far fewer PHLs were testing than expected. On February 21, when FDA requested clarification from CDC about the use of the authorized COVID-19 test, CDC “surprised FDA” by reporting that only seven PHLs were using the test. CDC assured FDA that the testing at these seven sites and increased testing capacity in CDC’s Atlanta facilities were meeting the needs of the nation.<sup>52</sup>

On February 24, FDA was again alerted to the possibility that U.S. testing needs were not being met by the CDC test. The Association of Public Health Laboratories (APHL) wrote to then FDA Commissioner Dr. Stephen Hahn to urge FDA to allow certain PHLs to immediately start using non-CDC tests developed in their own labs.<sup>53, 54</sup> Letters from APHL and other stakeholders also led FDA to recognize that many in the lab community did not know that they could have sought EUA for their own tests.<sup>55</sup> After receiving APHL’s letter, FDA began to join regular calls between CDC and APHL. FDA also started to consider policies to speed up test availability.

### *Actionable Insights*

- FDA addressed early testing challenges using EUA flexibilities, but this experience underscores the need for a national testing strategy.
- FDA needs clear, direct communication with the lab community during an emergency.

## **Facing the need for rapid expansion of COVID-19 testing, FDA eased EUA requirements to further speed getting tests to market**

As COVID-19 spread across the country, robust testing became increasingly urgent. The demand for diagnostic tests was growing exponentially and the pressure was high for FDA to take steps to immediately increase diagnostic test availability. This urgency increased after FDA learned that not as many PHLs were using CDC’s test as expected. In addition, serology tests were in demand to help researchers understand COVID-19 immunity and how the disease spreads.

To respond to this need, FDA took advantage of the flexibilities in the EUA process to address testing challenges the country was facing. Although the EUA process already allows developers to get their tests to the market faster than through traditional marketing pathways, FDA further eased various EUA requirements.

## To help developers overcome clinical sample shortages, FDA authorized tests using lower evidence standards

In mid-February 2020, FDA learned that developers were struggling to access clinical samples needed to validate tests, preventing them from requesting EUA. Although limited access to clinical samples is a typical problem when infectious diseases emerge outside of the U.S., this challenge became even more urgent in the wake of the CDC test rollout failure. Some samples were available in mid- to late February; however, only certain developers, such as those qualified to handle live viral material, could access the material. The larger developer community had limited access to clinical samples, or other kinds of acceptable validation material, until mid- to late March. Indeed, of the developers that responded to our survey and attempted to obtain validation material, 77 percent (173 out of 226) found obtaining validation materials to be challenging or somewhat challenging. FDA staff also told us that accessing validation material was the most common challenge reported to FDA early in the pandemic.

FDA responded by using its EUA flexibilities. FDA accepted validation studies that used contrived samples to help test developers overcome challenges accessing clinical samples. This was more achievable for developers, while

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“[The smaller set of samples] is just really, really a low bar. But [the] EUA process allows us to do that and match our requests to the situation on the ground.” – FDA official

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still demonstrating acceptable performance. On February 29, FDA announced that it would recommend that developers use a smaller set of patient samples, which FDA determined was just enough to be able to demonstrate acceptable performance. FDA also recommended that developers use more contrived samples than previously required.<sup>56, 57</sup> A contrived sample is made by “spiking” human specimens with COVID-19 material (such as inactivated virus).<sup>58, 59</sup> Although contrived samples are easier to access, they are less reliable than patient samples.<sup>60</sup> In total, FDA authorized 59 EUA requests based on validation using contrived samples, although in May 2020 FDA began to recommend clinical samples for validation since these were more easily available at this point.

Although FDA’s approach addressed the challenges of validating tests and getting them on the market faster, FDA also recognized that this approach introduced potential uncertainty into test results. As one FDA reviewer stated, “at the beginning of an outbreak we do have to compromise, and that’s really the nature of the outbreak.” To help address this uncertainty, FDA sent standardized validation material to all molecular test developers, including those that previously used contrived samples as well as those seeking EUA. Using this material allowed potential users of tests to compare performance results among tests.

### **Actionable Insight**

Developers require further FDA guidance on how to validate tests during shortages of clinical samples.

## **FDA allowed test developers to delay or forgo EUA review so that they could immediately begin testing**

FDA made several policy announcements to quickly increase the availability of tests (see Exhibit 4). These policies were “notification policies,” which meant that developers could delay or forgo FDA review and begin testing or distributing their tests right away, as long as they notified FDA and validated the tests first.

Within a week of FDA issuing the February 29 notification policy, which allowed qualified labs to begin testing before submitting an EUA request, seven labs notified FDA that they would begin testing. By late March, 65 labs notified FDA that they would test under this policy, and by May 11, 2.5 months after the original policy announcement, this increased to 245 labs.<sup>61, 62</sup>

Unlike the February 29 notification policy, FDA’s March 16 notification policy for commercial diagnostic test manufacturers generated little interest. An FDA official told us that relatively few commercial manufacturers took advantage of the policy and most chose to proceed with an EUA request before distributing their tests. While it is unclear why so few chose to take advantage of this policy, one developer that completed our survey and chose this route noted that, because its test had not yet received formal EUA, insurance payers did not pay for it.<sup>63</sup> Developers are also qualified for certain liability protections under the Public Readiness and Emergency Preparedness Act when their tests have EUA.<sup>64</sup>

**Exhibit 4. FDA issued five notification policies to increase test availability.\***

<b>Type of test</b>	<b>Date</b>	<b>Developers</b>	<b>Details</b>
<b>Diagnostic</b>	February 29	Certain labs qualified for high-complexity work	Before use, qualified labs must validate the test; notify FDA via email; submit a full request for EUA within 15 business days of notifying FDA.
	March 16	Commercial manufacturers	Before use and distribution, developers must validate the test; notify FDA via email; submit a EUA request within 15 business days of notifying FDA.
<b>Serology</b>	March 16	All developers	No EUA required if developer validates the test; notifies FDA; provides appropriate information with the test
	May 4	Commercial manufacturers	Revision to March 16 serology policy. Before use and distribution, developers must validate the test; notify FDA via email; submit a full request for EUA within 10 business days of notifying FDA.
<b>All tests</b> <sup>65</sup>	March 16 (March 12 for New York)	Certain labs qualified for high-complexity work	FDA granted flexibility for States to oversee COVID-19 tests developed and used by qualified labs within that State if the State notifies FDA first.

\*FDA no longer allows additional developers or States to use any notification policy as of November 15, 2021. Source: FDA Statements made on February 29, March 16, and May 4, 2020.<sup>66, 67, 68</sup>

FDA’s initial notification policy for serology tests, issued on March 16, allowed serology tests on the market with even more relaxed requirements than those for diagnostic tests. In mid-March, FDA stated that the value of serology tests lies mainly in advancing the scientific community’s understanding of COVID-19.<sup>69, 70</sup> Serology tests cannot be used to diagnose an active infection with COVID-19 and had limited use in prior emergencies.<sup>71</sup> Therefore, FDA made a strategic decision to focus its limited resources on authorizing diagnostic tests rather than serology tests. The March 16 notification policy stated that serology test developers could request EUA for their tests or put their test on the market without EUA if the developer met certain conditions. To help ensure that serology tests were used appropriately, FDA limited this policy to certain qualified labs.<sup>72, 73, 74</sup> By the end of April, 164 commercially manufactured serology tests were on the market via the notification policy.<sup>75</sup>

**To help test developers respond to supply shortages, FDA allowed developers to forgo seeking EUA amendments for substituting supplies**

When shortages emerged in March 2020, FDA recommended that developers use substitute supplies without an EUA amendment, which typically would have been

required. Manufacturers struggled to keep up with demand for certain supplies, such as reagents and nasal swabs, which the U.S. National Stockpile does not stock. When a developer demonstrated that an alternative product could be an acceptable substitute, FDA recommended that other developers make these substitutions without requesting an EUA amendment. To further support national efforts to address the supply shortage, FDA staff prioritized reviewing EUA submissions for tests that did not rely on supplies that were difficult to access.

FDA also took steps outside of its traditional role to ease supply shortages. Although FDA does not traditionally procure supplies, FDA worked with other government entities, including the Department of Defense (DoD) and the Federal Emergency Management Agency, to advise and coordinate procuring supplies. FDA worked with the Biomedical Advanced Research and Development Authority (BARDA) and DoD to coordinate military airlifts of swabs out of northern Italy to the U.S. In addition, FDA contacted over 1,000 manufacturers to gain insights on shortages and potential shortages, although it heard back from only around a third.<sup>76</sup> As one FDA official described FDA's approach to addressing testing supply shortages, FDA was "actively seeking and promoting different solutions to meet... the needs on the ground."

## **FDA's decisions to reduce or forgo EUA requirements allowed problematic tests on the market**

FDA successfully used the flexibilities in the EUA process to help make more tests available faster. However, when FDA allowed labs to use tests before requesting EUA, or to not require EUA at all, problems arose.

### **FDA found that many diagnostic tests on the market via the notification policies had performance problems**

FDA identified numerous tests with potential performance problems after issuing its notification policies for diagnostics tests. Indeed, although FDA designed its notification policies to expedite access to diagnostic tests, it was aware of potential tradeoffs with poorer test performance. Of the seven labs that notified FDA in the first week after the February 29 notification policy that they were going to start testing and submit an EUA request later, one lab ultimately withdrew its test due to contamination and three other labs had design or validation problems with their tests. A later FDA analysis of 125 EUA requests for lab-developed diagnostic tests found that 82 tests had design or validation problems. FDA identified similar problems with commercial tests.<sup>77</sup>

Problematic tests were on the market and being used for the time span between notification and FDA review and action.<sup>78</sup> Weeks or months may have passed before FDA reviewed the EUA request and required a developer to correct performance problems. This may have led to patients receiving false positive or false negative test results; the public health implications of the policy remain unclear. In addition,

because tests on the market via notification policies had not yet received EUA, developers of these tests did not have to meet conditions of authorization to report test performance concerns. To counter the delay in identifying problems, in May 2020 FDA began prioritizing review of tests on the market via the notification policy.

## **FDA determined that allowing developers to market serology tests with no EUA led to a concerning number of poorly performing and inappropriately marketed serology tests, which required FDA action**

Removing the requirement for EUA review allowed problematic serology tests on the market. By April 2020, around a month after the policy was announced, FDA became aware of a “flood” of poorly performing and inappropriately marketed serology tests.<sup>79, 80</sup> Some tests did not perform as expected, and others came with false claims to diagnose COVID-19 or to have FDA approval (no serology test for COVID-19 had FDA approval). Stakeholders were also using or considering using serology tests for purposes outside of advancing scientific knowledge.<sup>81, 82</sup> FDA officials have since publicly stated: “in hindsight, however, we realized that the policy outlined in our March 16 guidance was flawed” and point to this experience to show the importance of EUA review.<sup>83</sup>

Spurred by concerns about serology tests already on the market, FDA began to take actions. By the end of April, more than 150 serology tests were on the market without EUA.<sup>84</sup> That month, FDA issued a letter to health care providers cautioning them against using serology tests for diagnostic purposes and warning them about mislabeled tests.<sup>85, 86</sup> It also announced a

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“It’s to our knowledge that this is the first time the U.S. government has formally done testing of [in vitro diagnostic] products and used that testing to make regulatory decisions.”  
– FDA official

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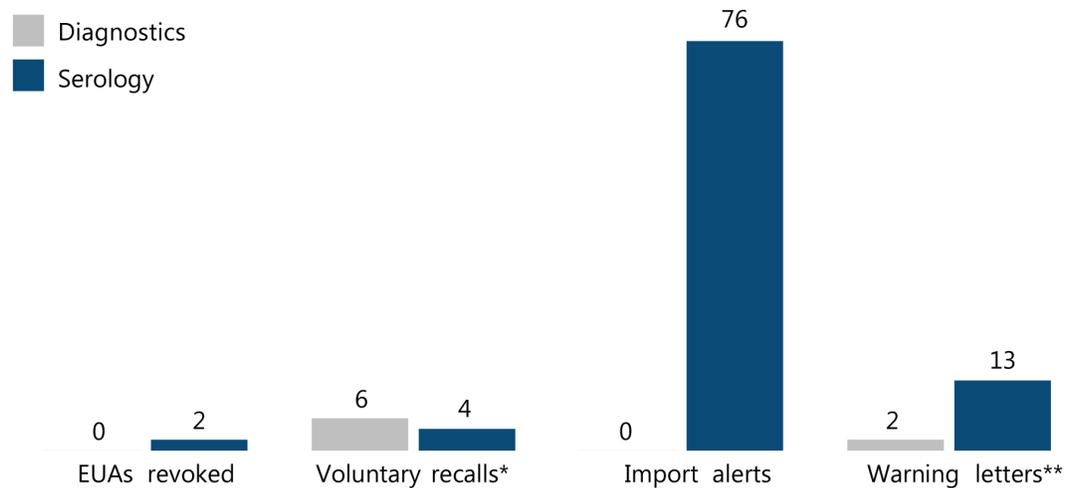
partnership with the National Institutes of Health, CDC, and BARDA to validate serology tests within the National Cancer Institute’s (NCI’s) labs. FDA worked with NCI to evaluate commercial manufacturers’ serology tests, both those already on the market via the notification policy and tests not yet on the market for which FDA needed additional data to support an EUA. FDA used the raw data sent by NCI to inform its regulatory decisions.<sup>87</sup> FDA posted performance reports for each evaluation on its website.<sup>88</sup> By early 2021, FDA found that two-thirds of EUA requests for serology tests that NCI evaluated did not have adequate performance data.

FDA took further action in May by requiring EUA review for certain tests already on the market. At this point, only 12 of the dozens of tests on the market had undergone EUA review (developers could still choose to request EUA under the March 16 notification policy).<sup>89</sup> On May 4, FDA announced a notification policy requiring commercial serology test manufacturers to request EUA within 10 business days of

putting validated tests on the market, including tests already on the market. Developers could still use and distribute their tests after requesting EUA. FDA required manufacturers that chose not to seek EUA to suspend distribution of their tests.<sup>90, 91</sup> In March, it created an online list of serology tests that it permits to remain on the market.<sup>92, 93</sup> By November 2020, FDA had removed 167 serology tests from this list.

In addition, most FDA post-authorization actions related to COVID testing in 2020 were for serology tests (see Exhibit 5). For example, FDA issued import alerts for nearly 80 inappropriately marketed serology tests that manufacturers from other countries were attempting to sell in the U.S. FDA issues import alerts to the public; devices on the import alert list are detained at the border and prevented from entering circulation until FDA receives evidence to overcome the appearance of the violation.<sup>94</sup>

**Exhibit 5. Throughout 2020, most post-authorization actions to address mislabeling and performance concerns for COVID-19 tests were for serology tests.**



\*Voluntary recalls are initiated by the manufacturer and conducted in accordance with 21 CFR Part 806.

\*\*This does not include two warning letters for entities offering violative serology and diagnostic tests.

Source: FDA data provided to OIG.

**Actionable Insight**

Although policies that delay or forgo FDA review allow for faster testing, without FDA review problematic tests reach the market.

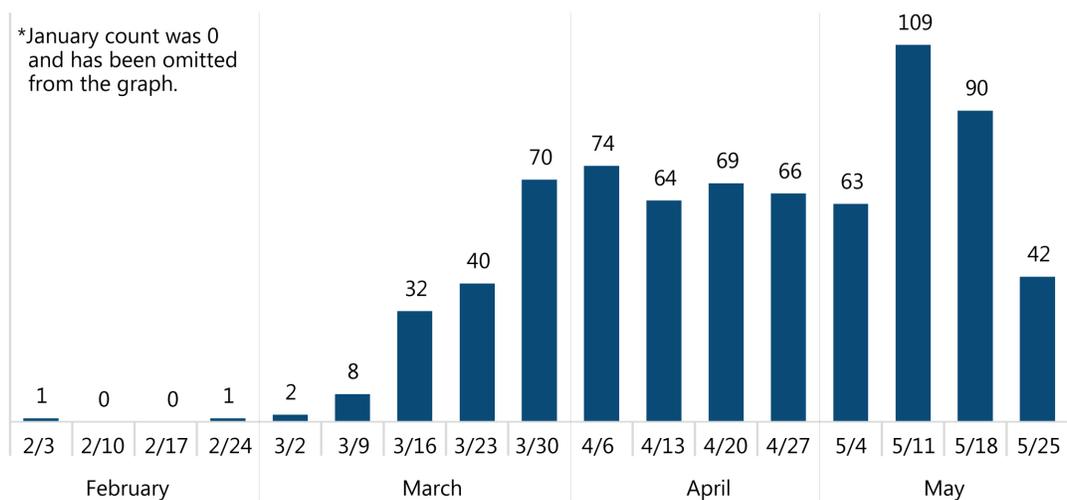
## A record number of EUA reviews led FDA to adjust its processes to better manage its workload, but some test developers were confused and frustrated by these changes

From January through May 2020, as demand for tests skyrocketed, FDA reviewed all EUA requests, regardless of the submission’s quality. An FDA official explained: “In the absence of a national testing strategy, ...we had to take an all-comers approach and it’s one of the reasons why there were so many tests authorized in the U.S. marketplace.” FDA reviewers interacted with developers primarily over email, working nights and weekends to authorize as many COVID-19 tests as possible. FDA developed new strategies to manage this unprecedented workload, but FDA staff were already overloaded with review work while they were spending additional time developing these strategies. In addition, some of FDA’s efforts frustrated and confused test developers.

### FDA reviewed a record number of EUA requests for COVID-19 tests, including a high number of low-quality submissions

Test developers inundated FDA with requests for EUAs in the first few months of the pandemic. According to an FDA official, FDA microbiology division staff process around 100 in vitro diagnostic test applications in a typical, nonpandemic year. During this study’s time frame of January through May 2020, FDA staff received over 100 EUA requests per *month* for 3 consecutive months (see Exhibit 6), which was in addition to their usual device approval work. In January 2021, nearly a year after the public health emergency began, the FDA official told us the volumes of requests were still over 100 per month.

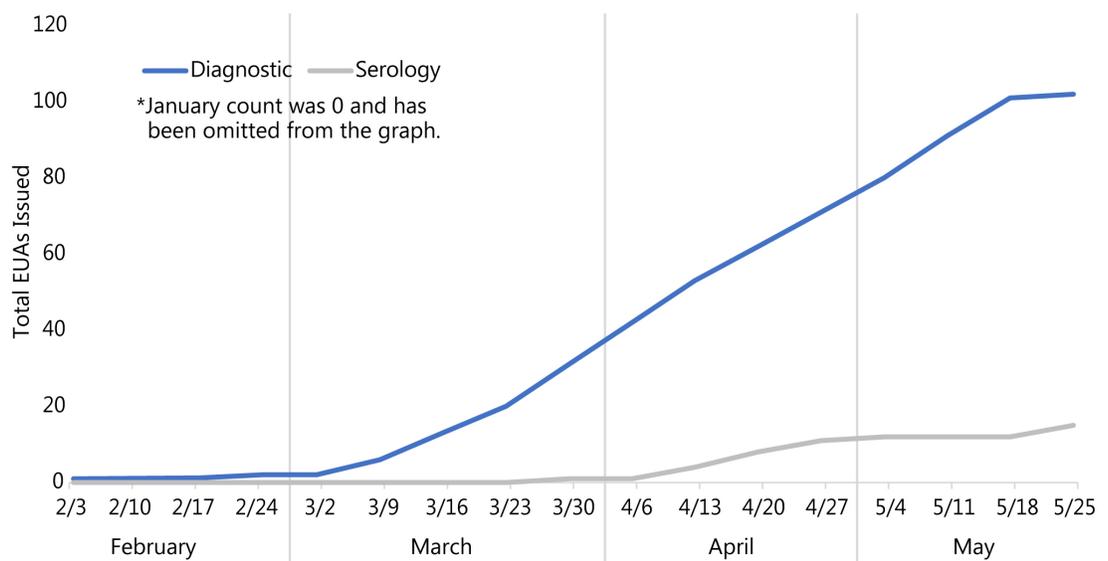
**Exhibit 6. EUA requests for COVID-19 tests increased substantially from February through May 2020.**



Note: FDA did not receive any EUA requests in January 2020.  
Source: FDA data provided to OIG.

During the first year of COVID-19, FDA issued more EUAs for tests than during all prior emergencies combined. For example, during the H1N1 influenza pandemic of 2009, the last pandemic to affect a large number of people in the U.S. prior to COVID-19, FDA issued 17 EUAs for H1N1 tests in a 12-month period.<sup>95</sup> In comparison, during the first 12-month period of the COVID-19 pandemic, FDA issued 320 EUAs for COVID-19 tests.<sup>96</sup> During our review period, January-May 2020, FDA authorized 117 tests (see Exhibit 7), and over the following 12 months, it authorized an additional 101 of the 731 tests that developers submitted for authorization during our review period.

**Exhibit 7. FDA issued over 100 EUAs for COVID-19 tests by the end of May 2020.**



Note: FDA did not issue any EUAs for COVID-19 tests in January 2020.

Source: FDA data provided to OIG.

Furthermore, FDA staff reported that most EUA submissions were low-quality, and this contributed to reviewer workload. Low-quality EUA submissions include those that were missing necessary data or contained data that failed to meet FDA’s standards. FDA reviewers communicated with test developers, requesting additional data and studies, until they could determine if the test met authorization standards. One lead reviewer estimated that 80 percent of submissions needed revisions.

“A lot of the submissions we got were very poor quality and all of that ate up our time.” – FDA official

Finally, developers inexperienced with FDA’s processes also took FDA reviewers’ time, which contributed to their heavy workloads. One reviewer told us, “it’s smaller device

manufacturers and laboratories who have not interacted with the regulatory environment much before, who struggle meeting our criteria.” In fact, most test developers that responded to OIG’s survey indicated that their experiences with FDA were limited: only 13 percent of respondents (31 of 237) had requested an EUA for a non-COVID-19 product in the past and just 28 percent of respondents (67 of 237) had gone through any FDA approval or clearance process at all. Experience appeared to help developers: 91 percent of survey respondents who had experience working with FDA on both an EUA and a regular device approval (20 of 22) received EUA for their first submitted COVID-19 test, compared to 40 percent of those with no experience (64 of 159). One FDA staff member who was responsible for responding to emails full-time for the first few months of the pandemic told us that those with less experience “had no idea... how things should be done” and required “another level” of support.

### *Actionable Insight*

FDA needs contingency plans for resources to handle the workload that the next emergency response may require.

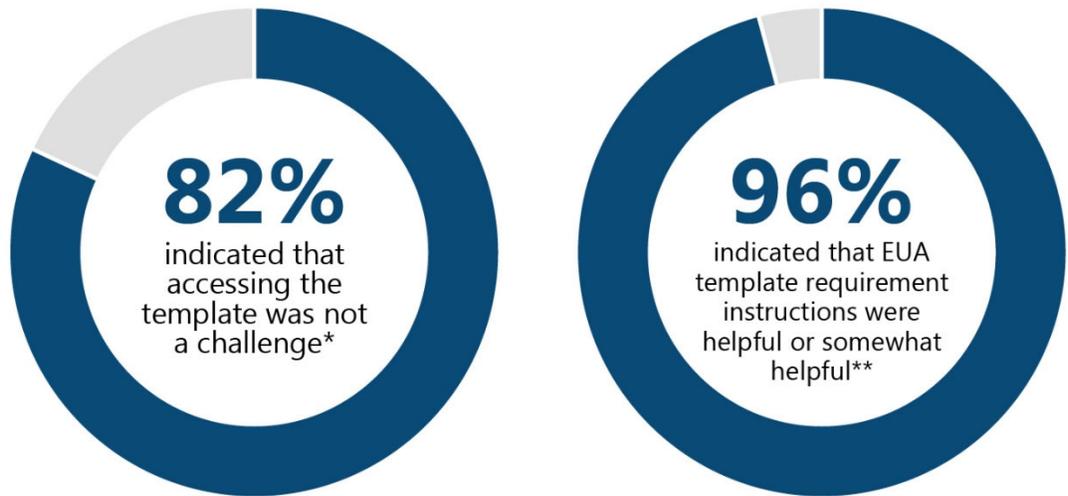
## **FDA spent time and resources offering special assistance to make the EUA process clear and accessible to test developers, but developers voiced concerns about evolving expectations**

Facing the urgent need for authorized tests, FDA took steps to make the EUA process clear and accessible to potential developers, many of which had never worked with FDA.

**Templates.** FDA developed templates for test developers to use in submitting EUA requests to FDA for COVID-19 tests. These templates provided a roadmap for developers to meet FDA’s standards for test development, validation, and authorization.<sup>97</sup> FDA created the templates based on feedback it had received from test developers in prior emergencies in which developers reported that FDA’s processes were not transparent.

Many test developers that responded to OIG’s survey benefitted from the templates (see Exhibit 8). For example, one test developer volunteered, “The difficulty was prior to Feb 29, 2020 when the obstacles were so high that we could not apply for an EUA and thus had no testing. When FDA changed the requirements and provided a template, it was much more straightforward.” Another explained how helpful it was to have a template to follow, saying it was “very clear in laying out exactly how we needed to validate our test and how we needed to present our validation data.”

**Exhibit 8. Developers who responded to OIG’s survey found FDA’s COVID-19 test templates accessible and helpful.**



\*191 out of 233 developers that accessed a test template  
\*\*222 out of 232 developers that used a template’s requirement instructions  
Source: OIG analysis of OIG survey data.

By May 31, FDA had revised one of its templates six times. FDA streamlined its original template for molecular tests by reducing it from 30 to 9 pages. FDA also modified the template to reflect new information and situations, such as knowledge about the virus or test component shortages. For example, FDA modified the template to recommend contrived samples for validating a test, and then modified it again when clinical samples were more widely available. This meant that a test developer that submitted its EUA request under the contrived samples template could be surprised to find that FDA would no longer accept its data by the time FDA began its review. The developer would then have to redo the same experiments with clinical samples to meet the requirements of the new template.

Adapting to FDA’s changing templates proved frustrating for some developers. In fact, 65 percent of developers that responded to our survey (153 out of 237) indicated that adapting to FDA’s changing requirements was challenging or somewhat challenging. In addition, FDA did

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“Between when I submitted my application for EUA and when it was reviewed, the template was changed. I found it difficult to follow the process, to know what was expected of my lab, and to keep up with the changes.” – Test developer, OIG survey

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not provide a template for antigen tests (e.g., rapid tests for home use) until May 11, 2020. Staff at one antigen test developer told us they were frustrated by FDA’s expectations for antigen test authorization, which they found particularly unclear prior to FDA releasing the antigen template. They, along with other survey respondents, reported having to resubmit data several times only for FDA to “move the goalpost” and deny EUA.

Nevertheless, FDA officials told us that the templates for the COVID-19 test EUA requests, and their revisions, allowed them to streamline their review and enabled authorization to occur more efficiently. Over time, templates came to include enough detailed information for test developers to submit a complete EUA request with minimal interaction with reviewers, including via pre-EUA. FDA emphasized the importance of creating templates that target different pathogens in advance of emergencies as a key lesson learned from this pandemic.

**Guidance documents.** FDA published guidance and updated policies on its website to further support test developers. For example, FDA published “Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency” on February 29, 2020, and revised it several times. Although 89 percent of test developers that responded to OIG’s survey (210 of 237) found the documents helpful or somewhat helpful, 65 percent (154 of 237) found keeping track of updates to FDA’s EUA policies challenging or somewhat challenging. One developer volunteered that it is “frustrating and costly... when new guidance or requirements are issued constantly.” Another was more specific in its criticism: “Conflicting guidances and being held to changing requirements in the EUA template dictated that experiments were performed multiple times at significant expense. This was not tenable and disrupted patient testing during the early stages of the pandemic.”

**Electronic submissions.** FDA changed its longstanding protocol of requiring developers to deliver all EUA requests in hard copy form. Experienced developers were accustomed to this requirement, but those that had not worked with FDA found it overly burdensome. Because this was a barrier for some developers during a time when the country urgently needed tests, FDA began accepting all submissions through email in February 2020.

**Dedicated email boxes for test developers.** To help manage the influx of emails from potential test developers, FDA initially created a general email box for stakeholders to direct questions about tests, supply shortages, and the EUA process. Because test developers quickly inundated the inbox with “thousands of emails,” FDA assigned two people to staff the email box 18-plus hours per day. FDA went further and

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“I cannot emphasize enough the convenience and how truly nice it was to have supplements and amendments be submitted to specific email boxes.” –  
Test developer, OIG survey

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created dedicated email boxes for specific aspects of the EUA process, such as an email box for test developers that had received an EUA to send amendment submissions when changes to a test became necessary. Of test developers that responded to our survey and used the email boxes, 89 percent (185 of 207) found them helpful or somewhat helpful. One developer told us it sent a few questions to the general email box and “whoever was working on that email box was very responsive.”

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“[T]he weekly FDA town hall calls that are ongoing have been a tremendous resource!”  
– Test developer, OIG survey

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**Town Halls.** In March 2020, FDA began holding weekly virtual Town Halls to provide developers the opportunity to ask technical questions about developing and validating COVID-19 tests. FDA also used Town Halls as an opportunity for experts to make announcements, answer general questions, listen to concerns to address on the call or take back to the Agency to consider, and give

developers insight into its review processes. An FDA official said all the major associations and other stakeholders participated; the official called the Town Halls “a great way to reach in the community very quickly.” Of test developers that responded to our survey and participated in the Town Halls, 89 percent (167 of 187) found them helpful or somewhat helpful.

**Frequently Asked Questions section of FDA’s website.** FDA added a FAQ section to its website in March 2020 to address questions related to COVID-19 tests and the EUA process. FDA updated the FAQ page frequently to address questions it received through emails. Of test developers that responded to our survey, 89 percent (211 of 237) found the FAQs helpful or somewhat helpful. For some, the FAQ page became a go-to source for updated information during the rapidly evolving pandemic. For example, one developer we interviewed would review the FAQ page “every single morning” during the first year of the pandemic.

### *Actionable Insights*

- Templates are useful tools for FDA to communicate expectations for test development, validation, and authorization.
- Inexperienced test developers require more support from FDA during the EUA process.

## FDA eased staff workload by adjusting its internal review process; test developers voiced frustration with a lack of transparency regarding these changes and the review process

In the face of the highest-ever volume of EUA requests, FDA told us it was short on staff. To assist reviewers, some staff with infectious disease experience from other FDA Centers transferred to CDRH. CDRH was also able to hire staff from outside FDA. Still, the volume of EUA submissions overwhelmed reviewers—one told us, “Our workload was unprecedented... I’m not sure if I’ve ever had 28 submissions on my workload. Not even half that.” This unsustainable workload impeded FDA’s ability to effectively respond to the pandemic.

In May 2020, after months of reviewing all tests submitted for EUA, FDA began adjusting internal review procedures to better manage its increasing EUA-related workload. A key component of the revised review procedures was the EUA prioritization policy that informally started in May 2020.<sup>98</sup> FDA prioritized review for tests that could increase accessibility (e.g., at-home tests), could enhance testing capacity (e.g., tests that allow processing of thousands of samples per day, per instrument), or were already allowed on the market without FDA review. FDA also began to decline to review some tests, such as those that processed low volumes, and declined to issue EUA for tests with incomplete EUA submissions rather than allowing developers to revise their submissions multiple times. FDA staff told us that the prioritization process was helpful in easing the strain on FDA resources and meeting public health needs.

However, some test developers reported that FDA’s prioritization policy was unclear. FDA first communicated the prioritization policy to the developer community during a Town Hall in May 2020. Developers that attended Town Halls reported being confused about the specifics of the prioritization policy. For example, one developer stated, “FDA did not give a direct answer to our questions about how they prioritize the applications for review.” In addition, not all developers attended Town Halls: 21 percent of our survey respondents (50 out of 237) did not and thus did not receive the message.

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“It was difficult to know why the FDA was not reviewing our application. It was unclear what the priorities were for review. It was unknown what a company could do to escalate review.” – Test developer, OIG survey

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Furthermore, some test developers that responded to our survey reported a lack of transparency from FDA on the status of their tests’ reviews. One stated that it did not receive “clear or formal communication when our EUA review paused and then was rejected as it was similar to an [existing] EUA test.” Others complained about not hearing from FDA for weeks or months while they waited for their tests to be reviewed. Some survey respondents expressed a desire for FDA to be more

transparent about the review process, and two specifically suggested that FDA should institute a tracking system so developers would know where their tests are in the process.

FDA did not finalize the prioritization policy until October 2020. By this time, some developers that received a “decline to review” decision, meaning their submission was deprioritized, had been awaiting FDA’s response for 5 months or more.

In November 2020, FDA took further steps to speed review and ease workload on reviewers by giving developers 24 to 48 hours to respond to their comments. According to survey respondents, responding to comments often includes rerunning studies and resubmitting data. If a test developer misses the time limit, then the reviewer may deny

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“[W]e were overwhelmed with submissions that had issues, and that would just take too long of a time to be resolved interactively. So we changed processes and limited the interactive review and set priorities for what the agency thought would address the public health need the most.” – FDA staff

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authorization. Thirty-two percent (76 out of 237) of developers that responded to our survey stated that meeting FDA’s time frames for data requests was challenging or somewhat challenging. Nevertheless, FDA suggested that limiting interactive review relieved workload and allowed reviewers to efficiently manage their EUA submissions.

# CONCLUSION AND RECOMMENDATIONS

FDA's experience using the EUA process during the first few months of the COVID-19 pandemic provided actionable insights about the EUA process as well as a national testing strategy.

## *Summary of Actionable Insights*

- FDA addressed early testing challenges using EUA flexibilities, but this experience underscores the need for a national testing strategy.
- FDA needs clear, direct communication with the lab community during an emergency.
- Developers require further FDA guidance on how to validate tests during shortages of clinical samples.
- Although policies that delay or forgo FDA review allow for faster testing, without FDA review problematic tests reach the market.
- FDA needs contingency plans for resources to handle the workload that the next emergency response may require.
- Templates are useful tools for FDA to communicate expectations for test development, validation, and authorization.
- Inexperienced test developers require more support from FDA during the EUA process.

Robust testing is crucial to responding to emergencies that involve infectious diseases. It not only identifies infected individuals but also promotes understanding of how a disease spreads. FDA's EUA authority offers FDA significant flexibility in how it can respond to testing needs during an emergency. FDA took advantage of this flexibility to help address CDC test problems and to increase testing availability. However, the U.S.'s early reliance on CDC as the sole manufacturer of its test, the inability to directly address sample and supply shortages, and resource limitations as FDA reviewers attempted to manage the influx of EUA reviews constrained FDA's response.

Balancing the need for test availability with test performance amidst an unprecedented pandemic was difficult for FDA to navigate. No roadmap existed to achieve that balance, so FDA made calculated decisions that prioritized testing availability. This meant that poorly performing tests reached the market, although how many were ultimately used or the impact on public health remains unknown.

Given the early experience of the pandemic, FDA has an opportunity to better plan for and respond to current and future public health emergencies. Indeed, FDA has

expressed its interest to apply lessons learned and be better positioned to facilitate testing that balances speed to market with quality. For example, FDA officials underscore the need for multiple entities to manufacture tests early in an outbreak. In addition, FDA is considering steps to ensure a shared understanding of nontraditional validation materials, such as synthetic material, to support EUA requests. This could include developing formal standards and guidelines on when it would be appropriate to use this material. Finally, an FDA official told us that FDA should be more engaged with communications among CDC and the lab testing community, including APHL.

To prepare for and respond to current and future emergencies, we recommend that FDA:

## **Assess and, as appropriate, revise FDA guidance for test EUA submissions**

FDA issued various policies to increase testing availability and to adjust review processes to manage increased EUA submission levels. FDA summarized and communicated these policies in a guidance document, which it issued without prior public comment because of the need to quickly respond to the pandemic. FDA should assess its use of these policies to determine whether and how it will implement them in future emergencies, and revise the policies to reflect lessons learned during the COVID-19 pandemic. Specifically, FDA should assess the following policies:

- **Developer notification policies:** In March 2020, FDA began to allow certain test developers to use validated tests before requesting EUA. FDA should assess the potential use of notification policies in future emergencies, including the appropriateness of additional safeguards to ensure adequate test performance for tests that have not yet undergone full EUA review.
- **Prioritization policies:** In May 2020, FDA began to adjust internal review processes to address its increasing workload and to meet public health goals. However, FDA did not finalize these revised review processes until later in 2020, leaving many developers confused as to the status of their EUA review. FDA should determine parameters for reviewing EUA submissions, including how to prioritize requests, how to communicate prioritization criteria to developers, and how to best leverage the criteria to address FDA's workload. FDA should clearly communicate these parameters to developers.

## **Develop a suite of EUA templates for future emergencies involving novel pathogens**

Templates were useful tools in the pandemic that supported developers requesting EUA for their tests. FDA recognizes the value in creating, in advance of an emergency,

templates that can be more quickly available to developers. Rather than developing new templates to support test developers as a novel pathogen emerges, as it did with COVID-19, FDA should aim to develop a suite of templates that will be ready at the start of an outbreak. FDA should adjust these as appropriate for the specifics of each outbreak. FDA should develop templates for both pathogen types that are commonly predicted to cause future outbreaks (e.g., from the WHO's list of such pathogens) and for various test types, such as rapid antigen tests.

Templates include key recommendations for how developers should validate their tests to meet FDA's requirements. When developing its suite of templates, FDA should determine appropriate validation standards for each pathogen and test type. This includes determining appropriate alternative validation materials for diagnostic tests, such as synthetic material, which developers may need to use to address any clinical sample access shortages. Such standards should include FDA's criteria on when it is appropriate to use these materials and what it expects for validating diagnostic tests with these materials.

To ensure transparency with the developer community, FDA should consult with stakeholders when developing templates, including validation recommendations, and FDA should post templates on its website.

## **Expand CDRH's existing device-tracking platform to facilitate EUA submission and monitoring**

For the period of our review, FDA managed its largest-ever volume of EUA requests primarily over email. Test developers reported that this sometimes led to confusion, including uncertainty about the status of their submissions. To support developers, FDA should modify its existing Customer Collaboration Portal (CCP), which allows developers to electronically track applications for devices submitted through certain traditional marketing pathways. Developers could use the CCP's existing features to view the status of their requests, including their review milestones, rather than reaching out to their reviewers for status updates. This would also reduce the burden on FDA reviewers to communicate updates to developers. FDA could add a data submission feature to this tool, which the CCP does not currently have. This would automate and consolidate the EUA submission process into one tool, which would help FDA and developers alike. While FDA has acknowledged the need to explore opportunities to modernize and improve its EUA supporting tools, it has not established any formal plans to do so.

## **Expand and improve resources for test developers on the EUA process**

FDA invested significant time and resources during the pandemic to support inexperienced test developers. FDA should develop technical guidance and educational material to ease some of its workload during any current and future

emergency response and to ensure that these resources are available to developers as early in an emergency as possible. To that end, FDA could develop EUA guidance tailored specifically to address gaps in developers' knowledge and experience, which FDA identified during the COVID-19 pandemic. This guidance could, for example, expand on FDA responses to FAQs from developers and provide updated instructions for how to access and use templates. It could also fill in gaps that left some test developers confused or frustrated, such as describing what FDA expects EUA submission data to look like and explaining what developers can expect in terms of communication from FDA.

FDA could also consider developing additional educational resources on the EUA process. These could include training webinars or step-by-step guides on how to request an EUA and how EUA requests are different from traditional marketing pathways. By carrying out these activities in advance, FDA will reduce its workload during emergencies as developers seek information on the EUA process.

In addition, FDA should continue the communication strategies that were successful during the COVID-19 pandemic to apply to current and future emergencies, as appropriate, particularly those that enhanced developer accessibility to FDA. These include Town Halls, FDA email inboxes, and FAQs.

## **Establish formal communication channels between FDA and the lab community, to be used in emergencies that require testing**

During the COVID-19 pandemic, FDA would have benefited from more direct communication with labs. For example, in February FDA was not aware that fewer PHLs were testing than it believed. Prior to the next emergency, FDA should work with key stakeholders in the lab community, such as APHL and the American Clinical Laboratory Association (ACLA), to determine how to communicate during and in advance of a public health emergency. FDA could consider creating regular forums for connecting during emergencies, including setting up protocols and expectations for when to initiate communications. During emergencies, FDA should use these channels to maintain close contact with these stakeholders to ensure that it receives direct information about emergency testing. In May 2022, FDA entered into a memorandum of understanding (MOU) with CDC and lab stakeholders (including APHL and ACLA).<sup>99</sup> We urge FDA to use this MOU as a starting point in building a collaborative relationship with CDC and the lab community before the next emergency.

## **Work with Federal partners to implement lessons learned about a national testing strategy outside the EUA process**

Early challenges with CDC's test rollout, clinical sample shortages, and an overwhelming workload shaped FDA's COVID-19 response. FDA should work closely with Federal partners to assess what they can do now to avoid similar challenges in

the future. This may be done by convening a formal panel of experts from each agency involved in emergency response preparations, or developing individual partnerships with one or more agencies to address specific challenges. At a minimum, FDA should coordinate with appropriate Federal partners to:

- Determine the feasibility of contracting with test manufacturers in advance of the next emergency. This would ensure that qualified manufacturers are on standby and could quickly produce well-designed, high-throughput tests at a volume appropriate to meet the needs of each emergency. It would also address manufacturers' hesitancy early in the pandemic to invest in a test for a novel disease, particularly without government incentives. Furthermore, it may circumvent testing delays in case one test or manufacturer encounters problems. FDA could seek a partnership with BARDA, which supports the development of diagnostic tests during emergencies, to accomplish this.
- Determine the feasibility of establishing a program to conduct all test validation to support EUAs during an emergency. Rather than requiring each developer to access its own validation materials, which may be limited early in an emergency, the Federal government could develop a program to conduct all validation during emergencies. Validation could occur on one or more sites, potentially with Federal partners. FDA could help expand existing partnerships with Federal agencies, such as NIH and CDC, that are currently assessing COVID-19 serology and over-the-counter tests. FDA uses data provided by these partners to inform its regulatory decisions. Such an approach may also help address problems with developer validation.
- Determine the feasibility of precertifying labs for emergency test development and use. FDA should consider a pre-emergency, nationwide effort to certify labs that are qualified to conduct emergency testing for emerging infectious diseases. Certified labs would not need to submit an EUA request for tests developed and used within that lab to respond to an emergency. Without so many EUAs to review, FDA could devote more resources to supporting less experienced test developers. Certified developers could begin using validated tests immediately. FDA could seek a partnership with the Centers for Medicare & Medicaid Services (CMS) to accomplish this, as CMS would have insight into laboratory qualifications given its oversight role.

On the basis of its findings for the assessments recommended above, FDA should implement all feasible recommendations.

# AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with all six of our recommendations, as detailed below.

First, FDA concurred with our recommendation to assess and, as appropriate, revise FDA guidance for test EUA submissions. We acknowledge that FDA has adapted its regulatory approach to address the public's testing needs throughout the COVID-19 pandemic. Given the importance of robust testing, especially in the early stages of a pandemic, adapting lessons learned from this pandemic related to developer notification and prioritization policies would position FDA to respond to current and future pandemics. We appreciate FDA's efforts thus far and look forward to the updates on the status of its assessment and revisions, if appropriate, to guidance in its Final Management Decision.

In concurring with our recommendation to develop a suite of EUA templates for future emergencies involving novel pathogens, FDA stated that its COVID-19 templates helped facilitate important conversations with test developers. FDA also reported that it has plans to engage test developers to create generic templates for commonly anticipated pathogens. Having general templates on hand and ready for the next novel pathogen can speed the EUA process and make it more efficient. In its Final Management Decision, FDA should include an update on the status of the templates.

FDA also concurred with our recommendation to expand CDRH's existing device-tracking platform to facilitate EUA submission and monitoring. We acknowledge FDA's efforts thus far to improve the EUA request process; adding tracking functionality would streamline the process and add transparency for stakeholders. Improving transparency, reducing duplicative efforts, and making the EUA submission process more efficient will help ensure that tests are available for use faster when the next novel pathogen emerges. FDA should detail in its Final Management Decision the steps it has taken to add EUA requests to its submission tracker tool.

Next, FDA concurred with our recommendation to expand and improve resources for test developers on the EUA process. In this report, we recommend that FDA continue the communication strategies that were successful during the COVID-19 pandemic, and FDA has indeed maintained these strategies. We look forward to FDA updates in its Final Management Decision on its progress to expand and improve resources for test developers, including technical guidance and educational material on the EUA process.

FDA concurred with our recommendation to establish formal communication channels between FDA and the lab community, to be used in emergencies that require testing. In this report, we urged FDA to use the MOU that it entered into with CDC and laboratory stakeholders as a starting point to build a collaborative

relationship with them and the lab community. FDA has already started to engage via this MOU for its response to monkeypox. Continuing to build and strengthen channels with the lab community will ensure that FDA maintains close contact with lab community stakeholders during current and future emergencies that require testing. We appreciate FDA's efforts thus far and look forward to further updates on the status of its efforts to establish these channels in its Final Management Decision.

Finally, FDA concurred with our recommendation to work with Federal partners to implement lessons learned about a national testing strategy outside the EUA process. We acknowledge that FDA has already communicated lessons learned through a variety of avenues. We ask that FDA describe the steps that it is taking, which may include convening a formal panel or developing individual partnerships, among other potential approaches in its Final Management Decision.

For the full text of FDA's comments, see the Appendix that follows this section.

# APPENDIX

## Appendix: Agency Comments

Following this page are the official comments from FDA.

**FDA's General Comments on on the OIG Draft Report, FDA Repeatedly  
Adapted Emergency Use Authorization Policies to Address the Need for COVID-19 Testing**

FDA appreciates the opportunity from the HHS Office of the Inspector General to review and comment on this draft report.

**General Comments**

**Recommendation 1**

FDA should assess and, as appropriate, revise guidance for test EUA submissions.

**FDA Response**

FDA concurs that it should assess and, as appropriate, revise guidance for test EUA submissions as the circumstances of PHEs warrant. Since the start of the COVID pandemic, FDA adapted its regulatory approach to address the public's testing needs, taking into account benefits and risks of providing additional flexibilities under the circumstances at the time. FDA continues to work closely with test developers to help them adjust as those needs have changed. These efforts have helped support increased testing capacity overall and broadened public access to rapid tests, including those purchased over the counter (OTC). In addition to at-home diagnostic tests, FDA's flexible policies have supported authorization of a myriad of options, including molecular and antigen tests, as well as serology tests; Point-Of-Care tests; home collection tests; multi-analyte tests that can detect both COVID-19 and flu; tests using various sample types, including saliva; and screening tests with pooling and serial testing. FDA made clear its review priorities, which were updated as appropriate. For example, FDA prioritized review of EUA requests that increased national testing capacity (e.g., for high throughput tests) or enhanced accessibility when needs indicated. Prioritization for tests allowed FDA to best allocate limited resources, which became critical as FDA faced an ever increasing and unprecedented number of EUA test submissions. The Agency continues to receive about 100 EUA requests and pre-EUA submissions each month for COVID-19 tests.

FDA also withdrew policies if and when the circumstances warranted. For example, when clinical specimens became widely available, FDA updated its policy to recommend their use in validation rather than contrived specimens. When FDA saw many serology tests coming to market that did not perform as claimed, including those claiming to diagnose COVID-19, the Agency discontinued its policy of no longer objecting to offering serology tests without first receiving EUA authorization.

As FDA continues to support the nation's response to COVID-19 and future PHEs, the Agency will carefully evaluate which policies are appropriate to support development of accurate and reliable tests and update them when circumstances warrant.

**Recommendation 2**

FDA should develop a suite of EUA templates for future emergencies involving novel pathogens.

## **FDA Response**

FDA concurs with OIG's recommendation. FDA had also received a similar recommendation from an independent study to develop a framework for how to conduct validation of diagnostic tests for emerging pathogens in the setting of a declared PHE. FDA plans to engage with test developers to establish generic templates for commonly anticipated pathogens that may be adapted for potential future outbreaks, as well as a framework for conducting appropriate validation under different circumstances, to speed the availability of future in vitro diagnostic (IVD) tests. FDA has noted these plans publicly here: [Emergency Use Authorization of COVID-19 Tests: Independent Assessment of the FDA's Response | FDA](#). In fact, stakeholders have reached out to engage with FDA, and we have received helpful feedback that we have already incorporated into our validation templates.

COVID-19 templates provided recommendations for test validation and a fill-in-the-blank form to streamline the paperwork and make it easier for developers to provide information in support of EUA requests. Since providing the first template in January 2020, FDA has been in daily contact with test developers to answer questions and help them through the EUA process. FDA had as many as ten posted templates and continues to update, add, combine, and remove templates as the science evolves and as necessary to support COVID-19 test developers. As of August 8, 2022, these templates have received over 6039 hits from those visiting FDA's website.

FDA notes that its templates provide recommendations based on FDA's experience, the state of the science, availability of validation material or other components, and the regulatory criteria to issue an EUA. Our recommendations are just that — recommendations. FDA is always open to alternative proposals from developers and will continue to consider those. More significant trade-offs in test accuracy may be appropriate where the need for availability and fast results is not being met. We found during the COVID-19 pandemic that our templates helped to facilitate these important conversations with developers and believe they will be critical in the future when we are faced with pathogens, both well-known and novel.

## **Recommendation 3**

FDA should expand the FDA Center for Devices and Radiological Health's existing device-tracking platform to facilitate EUA submission and monitoring.

### **FDA Response:**

FDA concurs with OIG's recommendation and notes that this is also consistent with a recommendation made by an independent study: [Emergency Use Authorization of COVID-19 Tests: Independent Assessment of the FDA's Response | FDA](#). In an effort to provide transparency, efficiency, and predictability for test developers, FDA has implemented improvements and streamlined its EUA review processes. From March 2020 to present, CDRH has identified IT system needs and implemented several improvements to facilitate EUA request submission tracking, including updating current systems to improve the tracking and management of EUA review and providing electronic submission (vs. mailing) capabilities for EUA submissions through our CDRH Submission Portal.

FDA plans to continue IT improvements that will streamline processes and improve transparency for sponsors, including adding EUA requests and other submissions to its submission tracker, though this will ultimately depend on resources.

FDA also notes that CDRH initiated a Digital Transformation Initiative in Fiscal Year (FY) 2016, which is ongoing. This initiative focuses on providing better IT infrastructures, technology solutions, and data to help both internal and external stakeholders across all regulatory programs. The goal is to improve transparency, reduce duplicative efforts, create an integrated environment, and help ensure that data are organized, curated properly, and accurate for decision making. This ongoing effort will help CDRH better track future EUA requests as well as provide better platforms for interacting with medical device sponsors when questions arise about their submissions.

#### **Recommendation 4**

FDA should expand and improve resources for test developers on the EUA process.

#### **FDA Response**

FDA concurs with OIG's recommendations. FDA had also received a related recommendation from an independent study to develop a framework for how to conduct validation of diagnostic tests for emerging pathogens in the setting of a declared PHE.<sup>1 2</sup> As noted in one of our previous responses, FDA plans to continue strengthening communication strategies and tools that have proven effective during the COVID-19 PHE, including town halls, webinars, a telephone hotline and email boxes for stakeholder inquiries, templates, and interactions with professional and trade organizations, and has already taken additional steps to do so.

As OIG's report acknowledges, FDA entered into a memorandum of understanding (MOU) with CDC and laboratory stakeholders (including APHL and ACLA) in May 2022, a formal step in further building collaborative relationships with the lab community. FDA is already fully engaged with CDC and developers under this MOU with respect to Monkeypox. Specifically, FDA is providing regulatory as well as clinical and technical diagnostics expertise to facilitate discussions about planning and implementing surge capacity for diagnostic testing. The Agency believes that even in this short time, the MOU has been helpful, particularly for allowing the USG to hear directly from laboratory professional associations and large commercial laboratories regarding:

- a. their willingness to test,
- b. what they are hearing in their interactions,
- c. where their pain points are,
- d. barriers to getting involved in any kind of response, and
- e. suggestions on next steps from their perspectives

In addition, FDA continues its regular town hall meetings for COVID-19 test developers and has started to include Monkeypox test announcements and updates during these sessions.

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<sup>1</sup> [Emergency Use Authorization of COVID-19 Tests: Independent Assessment of the FDA's Response | FDA](#)

<sup>2</sup> [Deliverable 15: Emergency Use Authorization Assessment - Final Report \(fda.gov\)](#)

The Agency also planned with CDC and participated in a Laboratory Biosafety Townhall on June 24, 2022, which was a collaboration with clinical and public health laboratory partners and instrument manufacturers discussing testing in laboratories during emergencies.<sup>3</sup>

These are just a few steps FDA has taken, in addition to incorporating stakeholder feedback into our templates.

### **Recommendation 5**

FDA should establish formal communication channels between FDA and the lab community, to be used in emergencies that require testing.

### **FDA Response**

FDA concurs with OIG's recommendations. FDA had also received a related recommendation from an independent study to develop a framework for how to conduct validation of diagnostic tests for emerging pathogens in the setting of a declared PHE.<sup>4 5</sup> As noted in one of our previous responses, FDA plans to continue strengthening communication strategies and tools that have proven effective during the COVID-19 PHE, including town halls, webinars, a telephone hotline and email boxes for stakeholder inquiries, templates, and interactions with professional and trade organizations, and has already taken additional steps to do so.

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- a. their willingness to test,
- b. what they are hearing in their interactions,
- c. where their pain points are,
- d. barriers to getting involved in any kind of response, and
- e. suggestions on next steps from their perspectives

In addition, FDA continues its regular town hall meetings for COVID-19 test developers and has started to include Monkeypox test announcements and updates during these sessions.

The Agency also planned with CDC and participated in a Laboratory Biosafety Townhall on June 24, 2022, which was a collaboration with clinical and public health laboratory partners and instrument manufacturers discussing testing in laboratories during emergencies.<sup>6</sup>

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<sup>3</sup> [CDC Town Hall Meeting on Laboratory Biosafety - Use of Laboratory Instruments, June 24, 2022](#)

<sup>4</sup> [Emergency Use Authorization of COVID-19 Tests: Independent Assessment of the FDA's Response | FDA](#)

<sup>5</sup> [Deliverable 15: Emergency Use Authorization Assessment - Final Report \(fda.gov\)](#)

<sup>6</sup> [CDC Town Hall Meeting on Laboratory Biosafety - Use of Laboratory Instruments, June 24, 2022](#)

These are just a few steps FDA has taken, in addition to incorporating stakeholder feedback into our templates.

### **Recommendation 6**

FDA should work with Federal partners to implement lessons learned about a national testing strategy that go beyond the EUA process.

### **FDA Response**

FDA concurs with OIG’s recommendation. We have already communicated lessons learned through a variety of avenues,<sup>7 8 9</sup> including the publication of two peer-reviewed articles<sup>10 11</sup> and will continue to work with Federal partners to try to implement them.

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<sup>7</sup> [Bending The Arc Of COVID-19 Test Development To Increase Access And Ensure Reliability— Now And In The Future | Health Affairs](#)

<sup>8</sup> [South Korea’s Implementation Of A COVID-19 National Testing Strategy | Health Affairs](#)

<sup>9</sup> [South Korea's Response to COVID-19: Focus on Testing Strategy and Lessons Learned \(fda.gov\)](#)

<sup>10</sup> [Covid-19 Molecular Diagnostic Testing — Lessons Learned | NEJM](#)

<sup>11</sup> [The FDA’s Experience with Covid-19 Antibody Tests | NEJM](#)

# ACKNOWLEDGMENTS AND CONTACT

Elizabeth Sandefer served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Sarah Hijaz and Malaena Taylor. Office of Evaluation and Inspections headquarters staff who provided support include Althea Hosein and Michael Novello.

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# ENDNOTES

- <sup>1</sup> The virus that causes COVID-19 is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). For readability, this report will refer to both the illness and the virus as COVID-19.
- <sup>2</sup> Michelle L. Holshue, Chas BeBolt, Scott Lindquist, Kathy H. Lofy, John Wiesman, Hollianne Bruce, Christopher Spitters, et al., "First Case of 2019 Novel Coronavirus in the United States," *New England Journal of Medicine*, March 5, 2020, 382: 929-936.
- <sup>3</sup> Although WHO did not declare COVID-19 a pandemic until March, for readability, this report will refer to the entire time period after COVID-19 emerged as "the COVID-19 pandemic" or "the pandemic."
- <sup>4</sup> World Health Organization, *Timeline: WHO's COVID-19 response*. Accessed at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline#> on April 11, 2022.
- <sup>5</sup> CDC, *Principles of Epidemiology in Public Health Practice*. Accessed at <https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html> on October 4, 2021.
- <sup>6</sup> CDC, *COVID Data Tracker*. Accessed at <https://covid.cdc.gov/covid-data-tracker/#datatracker-home> on May 25, 2022.
- <sup>7</sup> FDA, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*, May 11, 2020. Accessed at <https://www.fda.gov/media/135659/download> on September 21, 2021.
- <sup>8</sup> The World Health Organization first dispatched a diagnostic test for COVID-19 to its Regional Offices on February 2, 2020. World Health Organization, *Timeline: WHO's COVID-19 response*. Accessed at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline#event-46> on February 16, 2022.
- <sup>9</sup> FDA, *FDA Announced Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures*, January 27, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/fda-announces-key-actions-advance-development-novel-coronavirus-medical-countermeasures> on September 21, 2021.
- <sup>10</sup> 21 U.S.C. § 360bbb-3.
- <sup>11</sup> 21 CFR § 860.7.
- <sup>12</sup> FDA, *FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic*. Accessed at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic> on December 22, 2021.
- <sup>13</sup> The Secretary may also declare that circumstances exist to justify EUA for certain products based on significant potential of an emergency, without the declaration of a *public health* emergency. For the purposes of this report, we will use the term "emergency" to include public health emergencies.
- <sup>14</sup> 21 U.S.C. § 360bbb-3.
- <sup>15</sup> FDA, *Emergency Use Authorization*. Accessed at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> on March 20, 2020.
- <sup>16</sup> Federal Register, *Determination of Public Health Emergency*, February 7, 2020. Accessed at <https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency> on April 11, 2022.
- <sup>17</sup> 21 U.S.C. § 360bbb-3.
- <sup>18</sup> FDA, *Emergency Use Authorization*. Accessed at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> on March 20, 2020.
- <sup>19</sup> Test developers may request FDA approval or clearance to market and use their product. Test developers may seek approval or clearance during emergencies or nonemergencies.
- <sup>20</sup> 21 CFR § 860.7.
- <sup>21</sup> FDA, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*, May 11, 2020. Accessed at <https://www.fda.gov/media/135659/download?fbclid=IwAR3QjmFqN2BMNJq4IFCfDOnpogvsdsJdwM4pJFE1E1ItqNNRJ8zBjFUSOSQ> on October 5, 2021.
- <sup>22</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities*, January 2017. Accessed at [Emergency Use Authorization of Medical Products \(fda.gov\)](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) on September 21, 2021.
- <sup>23</sup> 21 U.S.C. § 360bbb-3.

---

<sup>24</sup> 21 CFR § 860.7.

<sup>25</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on May 25, 2022.

<sup>26</sup> Jeffrey Shuren, "FDA's Ongoing Work to Support and Advance COVID-19 Diagnostic Test Accuracy and Availability." Accessed at <https://www.fda.gov/news-events/fda-voices/fdas-ongoing-work-support-and-advance-covid-19-diagnostic-test-accuracy-and-availability> on September 23, 2021.

<sup>27</sup> Project BioShield Act of 2004, P.L. 108-276 July 21, 2004.

<sup>28</sup> FDA, *Emergency Use Authorizations for Medical Devices*. Accessed at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#coronavirus2013> on July 9, 2020.

<sup>29</sup> The Medical Device Amendments of 1976, P.L. 94-295, are codified largely in ch. V of the FDCA, §§ 501–573, 21 U.S.C. §§ 351–360ccc-2.

<sup>30</sup> FDA, *How to Determine If Your Product Is a Medical Device*. Accessed at <https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device> on September 29, 2021.

<sup>31</sup> FDA, *Center for Devices and Radiological Health*. Accessed at <https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health> on June 13, 2022.

<sup>32</sup> 21 U.S.C. § 360bbb-3.

<sup>33</sup> FDA, *FDA Virtual Town Hall Series- Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests*, September 23, 2020. Accessed at <https://www.fda.gov/media/142511/download> on October 7, 2021.

<sup>34</sup> FDA, *How to Submit a Pre-Emergency Use Authorization for In vitro Diagnostics to FDA*. Accessed at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda> on July 6, 2020.

<sup>35</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on May 25, 2022.

<sup>36</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on May 25, 2022.

<sup>37</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on May 25, 2022.

<sup>38</sup> FDA, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Guidance for Developers and Food and Drug Administration Staff*, November 15, 2021. Accessed at <https://www.fda.gov/media/135659/download> on May 27, 2022.

<sup>39</sup> 21 U.S.C. § 360bbb-3.

<sup>40</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on July 7, 2020.

<sup>41</sup> 21 U.S.C. § 360bbb-3.

<sup>42</sup> FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on May 25, 2022.

<sup>43</sup> FDA has also authorized other tests for the medical management of patients with COVID-19, but those are excluded from this study.

<sup>44</sup> FDA, *Important Information on the Use of Serological (Antibody) Tests for COVID-19 – Letter to Health Care Providers*, April 17, 2020. Accessed at: <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers> on September 21, 2021.

<sup>45</sup> FDA, *Coronavirus (COVID-19) Update: Daily Roundup May 29, 2020*, May 29, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-29-2020> on September 24, 2021.

<sup>46</sup> FDA, *FDA Roundup: May 3, 2022*. Accessed at <https://www.fda.gov/news-events/press-announcements/fda-roundup-may-3-2022> on May 3, 2022.

<sup>47</sup> Eighty-four of our 237 respondents developed more than one test for COVID-19, and many of these developers applied for EUA for more than one test. To avoid confusion, our survey questions specifically asked about each developer's *first* experience applying for EUA for a COVID-19 test.

<sup>48</sup> CDC, *Shipping of CDC 2019 Novel Coronavirus Diagnostic Test Kits Begins*, February 6, 2020. Accessed at <https://www.cdc.gov/media/releases/2020/p0206-coronavirus-diagnostic-test-kits.html> on December 9, 2021.

<sup>49</sup> Public health labs work with CDC during emergencies to conduct clinical diagnostic testing and disease surveillance, among other activities.

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- <sup>50</sup> FDA, *Coronavirus (COVID-19) Update: FDA expedited review of diagnostic tests to combat COVID-19*, March 30, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expedites-review-diagnostic-tests-combat-covid-19> on October 18, 2021.
- <sup>51</sup> Document submitted to the Homeland Security & Governmental Affairs Committee (2021).
- <sup>52</sup> Testimony from Robert Redfield to the House Foreign Affairs Subcommittee on Asia, the Pacific, and Nonproliferation. *Coronavirus Disease 2019: The U.S. and International Response*. Accessed at <https://www.cdc.gov/washington/testimony/2020/t20200127.htm> on March 3, 2022.
- <sup>53</sup> Letter to Grace Kubin, Director, Laboratory Services Section, Texas Department of State Health Services, and Scott J. Becker, Chief Executive Officer, Association of Public Health Laboratories, from Stephen M. Hahn, Commissioner, FDA, February 26, 2020. Accessed at <https://context-cdn.washingtonpost.com/notes/prod/default/documents/1bbf4d0e-8c11-4126-b3af-24a0575c0012/note/076de12e-172d-49e5-8c50-883688f9c999>. on August 11, 2022.
- <sup>54</sup> FDA, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics*, February 29, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics> on December 27, 2021.
- <sup>55</sup> FDA subsequently received letters from the New York State Department of Health, the New York City Department of Health and Mental Hygiene, the American Association for Clinical Chemistry, and the American Society for Microbiology, asking FDA to consider taking steps to allow certain labs to begin testing without EUA.
- <sup>56</sup> FDA reduced the number of positive specimens to the smallest number that would still statistically demonstrate acceptable test performance.
- <sup>57</sup> FDA, *Accelerated Emergency Use Authorization Templates for SARS-CoV-2 (COVID-19) Molecular Testing of Respiratory Specimens in CLIA Certified High-Complexity Laboratories*, March 7, 2020. Accessed at <https://asm.org/ASM/media/Article-Images/EUA-Covid19-Template.pdf> on April 11, 2022.
- <sup>58</sup> Jeffrey Shuren and Timothy Stenzel, "Covid-19 Molecular Diagnostic Testing – Lessons Learned," *The New England Journal of Medicine*, October 22, 2020, 383: e97.
- <sup>59</sup> FDA, *Accelerated Emergency Use Authorization Templates for SARS-CoV-2 (COVID-19) Molecular Testing of Respiratory Specimens in CLIA Certified High-Complexity Laboratories*, March 7, 2020. Accessed at <https://asm.org/ASM/media/Article-Images/EUA-Covid19-Template.pdf> on April 11, 2022.
- <sup>60</sup> Jeffrey Shuren and Timothy Stenzel, "Covid-19 Molecular Diagnostic Testing – Lessons Learned," *The New England Journal of Medicine*, October 22, 2020, 383: e97.
- <sup>61</sup> FDA, *Coronavirus (COVID-19) Update: Daily Roundup*, March 23, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup> on December 21, 2021.
- <sup>62</sup> FDA, *Coronavirus (COVID-19) Update: Daily Roundup May 11, 2020*, May 11, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-11-2020> on December 27, 2021.
- <sup>63</sup> The Coronavirus Aid, Relief, and Economic Security Act requires insurance payers to pay for EUA authorized tests as well as tests for which the developer requested or intends to request EUA. It is unclear why insurance payers did not pay for the developer's test in this instance.
- <sup>64</sup> P.L. 109–148.
- <sup>65</sup> As of November 2021, eight States and Puerto Rico notified FDA that they are operating under this flexibility. Labs in these States do not need to seek EUA or engage with FDA; thus, we were not able to assess the effect on testing for States that accepted this policy.
- <sup>66</sup> FDA, *Coronavirus (COVID-19) Update: FDA Issues New Policy to Help Expedite Availability of Diagnostics*, February 29, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-new-policy-help-expedite-availability-diagnostics> on December 27, 2021.
- <sup>67</sup> FDA, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics*, March 16, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help> on December 27, 2020.
- <sup>68</sup> Anand Shah and Jeffrey Shuren, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, May 4, 2020. Accessed at <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy> on December 27, 2021.
- <sup>69</sup> Anand Shah and Jeffrey Shuren, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, May 4, 2020. Accessed at <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy> on December 27, 2021.

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- <sup>70</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>71</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>72</sup> These are labs certified as high-complexity under the Clinical Laboratory Improvement Amendments (CLIA).
- <sup>73</sup> FDA, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics*, March 16, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help> on December 27, 2020.
- <sup>74</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>75</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>76</sup> The Coronavirus Aid, Relief, and Economic Security Act later extended FDA's authority to seek information about potential supply shortages.
- <sup>77</sup> Jeffrey Shuren and Timothy Stenzel, "Covid-19 Molecular Diagnostic Testing – Lessons Learned," *The New England Journal of Medicine*, October 22, 2020, 383: e97.
- <sup>78</sup> Jeffrey Shuren and Timothy Stenzel, "Covid-19 Molecular Diagnostic Testing – Lessons Learned," *The New England Journal of Medicine*, October 22, 2020, 383: e97.
- <sup>79</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>80</sup> Sheila Kaplan, "FDA Orders Companies to Submit Antibody Test Data," *The New York Times*, May 4, 2020. Accessed at [https://www.nytimes.com/2020/05/04/health/fda-antibody-tests-coronavirus.html?utm\\_campaign=pharmalittle&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=87429897&\\_hsenc=p2ANqtz-9gWqHfGuyPBVzNZbMBhjbNBI\\_qTPV3lwDtk7Y9eXG0I5lbbS4JQW4lfe9Ej--R0foxQzLAPZzhjVvYfXnvHDNNWJi1Bg&\\_hsmi=87429897](https://www.nytimes.com/2020/05/04/health/fda-antibody-tests-coronavirus.html?utm_campaign=pharmalittle&utm_source=hs_email&utm_medium=email&utm_content=87429897&_hsenc=p2ANqtz-9gWqHfGuyPBVzNZbMBhjbNBI_qTPV3lwDtk7Y9eXG0I5lbbS4JQW4lfe9Ej--R0foxQzLAPZzhjVvYfXnvHDNNWJi1Bg&_hsmi=87429897) on June 8, 2020.
- <sup>81</sup> FDA, *Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics*, March 16, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help> on December 27, 2020.
- <sup>82</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>83</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>84</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>85</sup> FDA, *Important Information on the Use of Serological (Antibody) Tests for COVID-19- Letter to Health Care Providers*, April 17, 2020. Accessed at <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers> on September 24, 2021.
- <sup>86</sup> FDA, *Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts*, April 18, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts> on October 21, 2021.
- <sup>87</sup> Jeffrey Shuren and Timothy Stenzel, "The FDA's Experience with Covid-19 Antibody Tests," *The New England Journal of Medicine*, February 18, 2021, 384:592-594.
- <sup>88</sup> FDA, *EUA Authorized Serology Test Performance*. Accessed at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance> on October 21, 2021.
- <sup>89</sup> Anand Shah and Jeffrey Shuren, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, May 4, 2020. Accessed at <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy> on December 27, 2021.
- <sup>90</sup> Anand Shah and Jeffrey Shuren, *Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy*, May 4, 2020. Accessed at <https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy> on December 27, 2021.

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<sup>91</sup> FDA, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, May 4, 2020. Accessed at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised> on October 5, 2021.

<sup>92</sup> FDA, *Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2*. Accessed at <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2> on October 21, 2021.

<sup>93</sup> FDA, *Coronavirus (COVID-19) Update: FDA Provides Promised Transparency for Antibody Tests*, May 21, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-promised-transparency-antibody-tests> on October 21, 2021.

<sup>94</sup> FDA, *Import Alerts*. Accessed at <https://www.fda.gov/industry/actions-enforcement/import-alerts> on June 29, 2022.

<sup>95</sup> FDA, *Historical Information about Device Emergency Use Authorizations*. Accessed at <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations> on December 27, 2021.

<sup>96</sup> FDA, *Coronavirus (COVID-19) Update: January 29, 2021*. Accessed at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-january-29-2021> on December 27, 2021.

<sup>97</sup> FDA, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*. Accessed at <https://www.fda.gov/media/135659/download> on September 21, 2021.

<sup>98</sup> FDA's EUA authority includes broad flexibility to set prioritization criteria for reviewing EUA requests. For example, FDA may prioritize certain tests for review to meet a public health goal such as maximizing capacity to process tests. See FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, January 2017. Accessed at <https://www.fda.gov/media/97321/download> on October 7, 2021.

<sup>99</sup> MOU 225-22-020. Accessed at <https://www.fda.gov/about-fda/domestic-mous/mou-225-22-020> on June 28, 2022.